

State of Utah
Administrative Rule Analysis
Revised May 2020

OUR File # 53284
DATE Filed 1-14-2021

NOTICE OF PROPOSED RULE

TYPE OF RULE: New ____; Amendment XXXX; Repeal ____; Repeal and Reenact ____

Utah Admin. Code Ref (R no.):	Title No. - Rule No. - Section No. R156-17b	Filing No. (Office Use Only)
Changed to Admin. Code Ref. (R no.):	R	

Agency Information

1. Department:	Commerce	
Agency:	Occupational and Professional Licensing	
Room no.:		
Building:	Heber M Wells	
Street address:	160 E 300 S	
City, state:	Salt Lake City, Utah 84111-2316	
Mailing address:	PO BOX 146741	
City, state, zip:	Salt Lake City, Utah 84114-6741	
Contact person(s):		
Name:	Phone:	Email:
Jennifer Falkenrath	801-530-7632	jzaelit@utah.gov

Please address questions regarding information on this notice to the agency.

General Information

2. Rule or section catchline:

Pharmacy Practice Act Rule

3. Purpose of the new rule or reason for the change (If this is a new rule, what is the purpose of the rule? If this is an amendment, repeal, or repeal and reenact, what is the reason for the filing?):

This filing is made to conform the rules to statutory changes made by S.B. 145, S.B.157, H.B. 24, and H.B. 207 passed during the 2020 General Legislative Session. These bills amended the Pharmacy Practice Act regarding dispensing scope of practice for pharmacist and pharmacy interns, and changed the requirements for the charitable prescription drug recycling program. Additionally, the Division in collaboration with the Board of Pharmacy recommends certain amendments to the preceptor language to reflect the current practice in the profession.

4. Summary of the new rule or change:

The amendments to Sections R156-17b-303a, R156-17b-303b, R156-17b-303c, R156-17b-602, R156-17b-614d and R156-17b-614g, delete language for an eliminated registration type and makes nonsubstantive formatting changes for clarity.

Section R156-17b-305 is deleted in its entirety to align with Board recommendations regarding endorsement pursuant to SB 23 passed during the 2020 General Legislative Session.

Section R156-17b-402 updates the fine schedule to add a fine for violation of Section 58-17b-502(1)(p) in accordance with H.B. 24 passed during the 2020 General Legislative Session.

The amendments to section R156-17b-606 updates the preceptor language to align with current internship and preceptor standards in the profession.

The new Section R156-17b-612a establishes operating standards for a pharmacist or pharmacy intern to dispense a prescription device pursuant to a prescriber's prescription.

The new section R156-17b-612b establishes operating standards for a pharmacist to dispense a refill of insulin pursuant to an exhausted prescription.

The new section R156-17b-626 creates operating standards for a pharmacist or pharmacy intern to make appropriate substitutions for albuterol.

Sections R156-17b-904 through R156-17b-907e are consolidated into one new Section R156-17b-901 for the Charitable Prescription Drug Recycling Program, and the provisions are amended to update the requirements for registration in accordance with Subsection 58-17b-902(8)(b) as amended by S.B. 157.

Fiscal Information

5. Aggregate anticipated cost or savings to:

A) State budget:

None of these proposed changes are expected to impact state government revenues or expenditures because the changes merely update the rules to establish operating standards that encompass current statutory requirements and current practices in the profession, and make formatting changes for clarity.

B) Local governments:

These proposed amendments will affect businesses in the pharmacy industry that employ pharmacists and pharmacy interns, and this may potentially include certain local government entities acting as businesses. However, the Division estimates that these proposed amendments will have no fiscal impact on local governments because the changes merely update the rules to establish operating standards that encompass current statutory requirements and current practices in the profession, and make formatting changes for clarity. These amendments are based on extensive collaboration with the Board of Pharmacy and the Physician Board to update the rules in accordance with the statutory changes and incorporate and codify existing generally accepted professional standards common in the industry.

C) Small businesses ("small business" means a business employing 1-49 persons):

These proposed amendments will affect small businesses in the pharmacy industry that employ pharmacists and pharmacy interns. However, the Division estimates that these proposed amendments will have no fiscal impact on small business revenues or expenditures because the changes merely update the rules to establish operating standards that encompass current statutory requirements and current practices in the profession, and make formatting changes for clarity. These amendments are based on extensive collaboration with the Board of Pharmacy and the Physician Board to update the rules in accordance with the statutory changes and incorporate and codify existing generally accepted professional standards common in the industry.

D) Non-small businesses ("non-small business" means a business employing 50 or more persons):

These proposed amendments will affect non-small businesses in the pharmacy industry that employ pharmacists and pharmacy interns. However, the Division estimates that these proposed amendments will have no fiscal impact on non-small business revenues or expenditures because the changes merely update the rules to establish operating standards that encompass current statutory requirements and current practices in the profession, and make formatting changes for clarity. These amendments are based on extensive collaboration with the Board of Pharmacy and the Physician Board to update the rules in accordance with the statutory changes and incorporate and codify existing generally accepted professional standards common in the industry.

E) Persons other than small businesses, non-small businesses, state, or local government entities ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an **agency**):

No other persons are expected to be impacted by these amendments because the changes merely update the rules in accordance with statutory changes and codify existing generally accepted professional standards common in the industry.

F) Compliance costs for affected persons:

There are no compliance costs expected for affected persons because the changes merely update the rules in accordance with statutory changes and codify existing generally accepted professional standards common in the industry.

G) Regulatory Impact Summary Table (This table only includes fiscal impacts that could be measured. If there are inestimable fiscal impacts, they will not be included in this table. Inestimable impacts will be included in narratives above.)

Regulatory Impact Table

Fiscal Cost	FY2021	FY2022	FY2023
State Government	\$0	\$0	\$0
Local Governments	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0
Other Persons	\$0	\$0	\$0
Total Fiscal Cost	\$0	\$0	\$0

Fiscal Benefits			
State Government	\$0	\$0	\$0
Local Governments	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0
Other Persons	\$0	\$0	\$0
Total Fiscal Benefits	\$0	\$0	\$0
Net Fiscal Benefits	\$0	\$0	\$0

H) Department head approval of regulatory impact analysis:

The head of the Department of Commerce, Margaret W. Busse, has reviewed and approved this fiscal analysis.

6. A) Comments by the department head on the fiscal impact this rule may have on businesses:

The Division of Occupational and Professional Licensing proposes amendments to the Utah Pharmacy Practice Act Rule. This filing harmonizes the statutory changes with the corresponding rule made by S.B. 145, S.B.157, H.B. 24, and H.B. 207 passed during the 2020 General Legislative Session. These bills amended the Pharmacy Practice Act relating to the scope of practice for pharmacist and pharmacy interns and changed the requirements for the prescription drug recycling program. Further, the Division in conference with the Board of Pharmacy have made minor amendments to update references and clarify the rule.

Small Businesses (less than 50 employees):

These amendments to the rule should have no expected fiscal impact to small businesses in Utah practicing in pharmacy (NAICS code 446110). Although these proposed amendments will affect small businesses in the pharmacy industry that employ pharmacists and pharmacy interns, the Division estimates that these proposed amendments will have no fiscal impact on small business revenues or expenditures because the changes are updating the rules to establish operating standards that currently exist in the statute. Further, no fiscal impact is expected for small business over and above any fiscal impact described in the legislative fiscal notes S.B. 145, S.B. 157, H.B. 24, and H.B. 207 in the 20202 General Session as these costs are either inestimable or there is no fiscal impact.

Regulatory Impact to Non-Small Businesses (50 or more employees)

These amendments will have no expected fiscal impact for non-small pharmacy businesses in Utah (NAICS code 446110) as described above for small business. These costs are either inestimable, for the reasons stated above, or there is no fiscal impact.

B) Name and title of department head commenting on the fiscal impacts:

Margaret W. Busse, Interim Executive Director

Citation Information

7. This rule change is authorized or mandated by state law, and implements or interprets the following state and federal laws. State code or constitution citations (required):

Section 58-17b-101	Subsection 58-17b-601(1)	Section 58-37-1
Subsection 58-1-106(1)(a)	Subsection 58-1-202(1)	

Incorporations by Reference Information

(If this rule incorporates more than two items by reference, please include additional tables.)

8. A) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; if none, leave blank):

First Incorporation	
Official Title of Materials Incorporated (from title page)	
Publisher	
Date Issued	
Issue, or version	

B) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; if none, leave blank):

Second Incorporation**Official Title of Materials Incorporated
(from title page)****Publisher****Date Issued****Issue, or version****Public Notice Information**

9. The public may submit written or oral comments to the agency identified in box 1. (The public may also request a hearing by submitting a written request to the agency. The agency is required to hold a hearing if it receives requests from ten interested persons or from an association having not fewer than ten members. Additionally, the request must be received by the agency not more than 15 days after the publication of this rule in the *Utah State Bulletin*. See Section 63G-3-302 and Rule R15-1 for more information.)

A) Comments will be accepted until (mm/dd/yyyy):

03/03/2021

B) A public hearing (optional) will be held:**On (mm/dd/yyyy):**

02/23/2021

At (hh:mm AM/PM):

8:30 AM

At (place):

For electronic Google Meets information for this rule hearing, please see the Utah State Board of Pharmacy February 23, 2021 agenda for this meeting date on the PMN website.

10. This rule change MAY become effective on (mm/dd/yyyy): 03/10/2021

NOTE: The date above is the date on which this rule MAY become effective. It is NOT the effective date. After the date designated in Box 10, the agency must submit a Notice of Effective Date to the Office of Administrative Rules to make this rule effective. Failure to submit a Notice of Effective Date will result in this rule lapsing and will require the agency to start the rulemaking process over.

Agency Authorization Information

To the agency: Information requested on this form is required by Sections 63G-3-301, 302, 303, and 402. Incomplete forms will be returned to the agency for completion, possibly delaying publication in the *Utah State Bulletin*, and delaying the first possible effective date.

**Agency head or
designee, and title:** Mark B. Steinagel, Director**Date
(mm/dd/yyyy):** 01/14/2021

R156. Commerce, Occupational and Professional Licensing.

R156-17b. Pharmacy Practice Act Rule.

R156-17b-303a. Qualifications for Licensure - Education Requirements.

(1) In accordance with Subsections 58-17b-303(2) and 58-17b-304([7]6)(b), the credentialing agency recognized to provide certification and evaluate equivalency of a foreign educated pharmacy graduate is the Foreign Pharmacy Graduate Examination Committee (FPGEC) of the National Association of Boards of Pharmacy Foundation.

(2) In accordance with Subsection 58-17b-304([7]6), an applicant for a pharmacy intern license shall demonstrate that the applicant meets one of the following education criteria:

(a) current admission in a college of pharmacy accredited by the ACPE, by written verification from a dean of the college;

(b) a graduate degree from a school or college of pharmacy that is accredited by the ACPE; or

(c) a graduate degree from a foreign pharmacy school as established by a certificate of equivalency from an approved credentialing agency defined in Subsection (1).

(3) In accordance with Subsection 58-17b-305(1)(f), a pharmacy technician shall complete a training program that is:

(a) accredited by ASHP; or

(b) conducted by:

(i) the National Pharmacy Technician Association;

(ii) Pharmacy Technicians University; or

(iii) a branch of the Armed Forces of the United States, and

(c) meets the following standards:

(i) completion of at least 180 hours of directly supervised practical training in a licensed pharmacy as determined appropriate by a licensed pharmacist in good standing; and

(ii) written protocols and guidelines for the teaching pharmacist outlining the utilization and supervision of pharmacy technician trainees that address:

(A) the specific manner in which supervision will be completed; and

(B) an evaluative procedure to verify the accuracy and completeness of ~~all~~any act[s], task[s] and function[s] performed by the pharmacy technician trainee.

(4) An individual shall complete a pharmacy technician training program and successfully pass the required examination as listed in Subsection R156-17b-303c(4) within two years after obtaining a pharmacy technician trainee license, unless otherwise approved by the Division in collaboration with the Board for good cause showing exceptional circumstances.

(a) Unless otherwise approved under Subsection (4), an individual who fails to apply for and obtain a pharmacy technician license within the two-year time frame shall repeat a pharmacy technician training program in its entirety if the individual pursues licensure as a pharmacy technician.

(5)(a) Pharmacy technician training programs that received Division approval on or before April 30, 2014 are exempt from satisfying standards ~~established~~in Subsection R156-17b-303a(3) for students enrolled on or before December 31, 2018.

(b) A student in a program described in Subsection (5)(a) shall comply with the program completion deadline and testing requirements in

Subsection (4), except that the license application shall be submitted to the Division no later than December 31, 2021.

(c) A program in ASHP candidate status shall notify a student prior to enrollment that if the program is denied accreditation status while the student is enrolled in the program, the student will be required to complete education in another program with no assurance of how many credits will transfer to the new program.

(d) A program in ASHP candidate status that is denied accreditation shall immediately notify the Division, enrolled students and student practice sites, of the denial. The notice shall instruct each student and practice site that:

(i) the program no longer satisfies the pharmacy technician license education requirement in Utah; and

(ii) enrollment in a different program meeting requirements established in Subsection R156-17b-303a(3) is necessary for the student to complete training and to satisfy the pharmacy technician license education requirement in Utah.

(6) An applicant from another jurisdiction seeking licensure as a pharmacy technician in Utah ~~[is deemed to have met]~~ meets the qualifications for licensure in Subsection 58-17b-305(1) ~~([f]e)~~ and 58-17b-305(1) ~~([g]f)~~ if the applicant:

(a) has engaged in the practice of a pharmacy technician for a minimum of 1,000 hours in that jurisdiction within the past two years or has equivalent experience as approved by the Division in collaboration with the Board; and

(b) has passed and maintained current PTCB or ExCPT certification.

R156-17b-303b. Qualifications for Licensure - Pharmacist - Pharmacy Internship Standards.

(1) In accordance with Subsection 58-17b-303(1) ~~([g]f)~~, the [following standards are established for the] pharmacy internship standards required for licensure as a pharmacist are established in this section. [+]

~~([1]2)~~ A ~~For~~ graduate[s] of ~~[all]~~ a U.S. pharmacy school[s] shall have at [+]

~~(a) At~~ least 1,740 hours of practice ~~[supervised by a pharmacy preceptor shall be]~~ obtained according to the Accreditation Council for Pharmacy Education (ACPE), Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree, effective July 1, 2016 ("Standards 2016"), which is hereby incorporated by reference.

(3) (a) A graduate of a foreign pharmacy school shall have at least 1,440 hours of supervised pharmacy practice in the United States.

(b) The Division in collaboration with the Board may credit up to 500 hours towards the requirement of Subsection (2)(a) for a graduate's other experience substantially related to the practice of pharmacy.

~~([b]4)~~ If a pharmacy intern is suspended or dismissed from an approved College of Pharmacy, the pharmacy intern shall notify the Division within 15 days of the suspension or dismissal.

~~([e]5)~~ If a pharmacy intern ceases to meet ~~[all]~~ each requirement[s] for intern licensure, the pharmacy intern shall surrender the pharmacy intern license to the Division within 60 days unless an extension is

requested and granted by the Division in collaboration with the Board. [

~~(2) For graduates of all foreign pharmacy schools, at least 1,440 hours of supervised pharmacy practice in the United States.~~

~~(3) Up to 500 hours towards the requirements of Subsections (1)(a) or (2) may be granted, at the discretion of the Division in collaboration with the Board, for other experience substantially related to the practice of pharmacy.]~~

R156-17b-303c. Qualifications for Licensure - Examinations.

(1) In accordance with Subsection 58-17b-303(1)([h]g), the examinations that shall be [successfully] passed by an applicant for licensure as a pharmacist are:

(a) the NAPLEX with a passing score as established by NABP; and

(b) the Utah Multistate Pharmacy Jurisprudence Examination (MPJE) with a minimum passing score as established by NABP.

(2)(a) An individual who has failed either examination three times shall meet with the Board to request an additional authorization to test.

(b) The Division, in collaboration with the Board, may require additional training as a condition for approval of an authorization to retest.

(3) In accordance with Subsection 58-17b-303(3)([j]i), an applicant applying by endorsement [is required to] shall pass the Utah MPJE.

(4)(a) In accordance with Subsection 58-17b-305(1)([g]f), an applicant applying for licensure as a pharmacy technician shall pass the PTCB or ExCPT with a passing score as established by the certifying body.

(b) The certificate shall exhibit a valid date and that the certification is active.

(5) A graduate of a foreign pharmacy school shall obtain a passing score on the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination.

~~**[R156-17b-305. Qualifications for Licensure - Pharmacist by Endorsement.**~~

~~In accordance with Subsections 58-17b-303(3) and 58-1-301(3), an applicant for licensure as a pharmacist by endorsement shall:~~

~~(1) apply through the "Licensure Transfer Program" administered by NABP;~~

~~(2) have obtained sufficient continuing education credits to maintain a license to practice pharmacy in the state of practice; and~~

~~(3) not had a pharmacist license suspended, revoked, canceled, surrendered, or otherwise restricted for any reason in any state for ten years prior to application in Utah, unless otherwise approved by the Division in collaboration with the Board.]~~

R156-17b-402. Administrative Penalties.

In accordance with Subsection 58-17b-401(6) and Sections 58-17b-501 and 58-17b-502, unless otherwise ordered by the presiding officer, the following fine and citation schedule shall apply:

TABLE

FINE SCHEDULE

VIOLATION	FIRST OFFENSE	SUBSEQUENT OFFENSE
58-1-501(1) (a)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501(1) (b)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501(1) (c)	\$ 500 - \$ 1,000	\$ 1,000 - \$ 5,000
58-1-501(1) (d)	\$ 500 - \$ 1,000	\$ 1,000 - \$ 5,000
58-1-501(1) (e)	\$ 100 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501(1) (f) (i) (A)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501(2) (m) (i)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501(1) (f) (i) (B)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501(2) (m) (ii)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501(2) (a)	\$ 100 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501(2) (b)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501(2) (c)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501(2) (d)	\$ 100 - \$ 500	\$ 200 - \$ 1,000
58-1-501(2) (e)	\$ 100 - \$ 500	\$ 200 - \$ 1,000
58-1-501(2) (f)	\$ 100 - \$ 500	\$ 200 - \$ 1,000
58-1-501(2) (g)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501(2) (h)	\$ 100 - \$ 500	\$ 200 - \$ 1,000
58-1-501(2) (i)	\$ 100 - \$ 500	\$ 200 - \$ 1,000
58-1-501(2) (j)	\$ 100 - \$ 500	\$ 200 - \$ 1,000
58-1-501(2) (k)	\$ 100 - \$ 1,000	\$ 500 - \$ 2,000
58-1-501(2) (l)	\$ 100 - \$ 500	\$ 200 - \$ 1,000
58-1-501(2) (n)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-1-501.5	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
R156-1-501(1)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
R156-1-501(2)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
R156-1-501(3)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
R156-1-501(4)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
R156-1-501(5)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
R156-1-501(6)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
58-17b-501(1)	\$ 500 - \$ 2,000	\$ 5,000
58-17b-501(2)	\$ 100 - \$ 1,000	\$ 500 - \$ 2,000
58-17b-501(3) (a)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-17b-501(3) (b)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-17b-501(4)	\$ 1,000 - \$ 5,000	\$10,000
58-17b-501(5)	\$ 100 - \$ 500	\$ 200 - \$ 1,000
58-17b-501(6)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-17b-501(7)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-17b-501(8)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
58-17b-501(9)	\$ 500 - \$ 1,000	\$ 1,500 - \$ 5,000
58-17b-501(10)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
58-17b-501(11)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
58-17b-501(12)	\$ 1,000 - \$ 5,000	\$10,000
58-17b-501(13)	\$ 100 - \$ 500	\$ 1,000 - \$ 2,500
58-17b-502(1) (a)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
58-17b-502(1) (b)	\$ 2,500 - \$ 5,000	\$ 5,500 - \$10,000
58-17b-502(1) (c)	\$ 1,000 - \$ 5,000	\$10,000
58-17b-502(1) (d)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000

58-17b-502(1) (e)	\$ 1,000 - \$ 5,000	\$10,000
58-17b-502(1) (f)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
58-17b-502(1) (g)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
58-17b-502(1) (h)	\$ 100 - \$ 500	\$ 500 - \$ 1,000
58-17b-502(1) (i)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
58-17b-502(1) (j)	\$ 100 - \$ 500	\$ 500 - \$ 1,000
58-17b-502(1) (k)	\$ 100 - \$ 500	\$ 2,000 - \$10,000
58-17b-502(1) (l)	\$ 100 - \$ 500	\$ 500 - \$ 1,000
58-17b-502(1) (m)	\$ 500 - \$ 1,000	\$ 2,500 - \$ 5,000
58-17b-502(1) (n)	\$ 100 - \$ 500	\$ 500 - \$ 1,000
58-17b-502(1) (o)	\$ 100 - \$ 500	\$ 500 - \$ 1,000
58-17b-502(1) (p)	\$ 2,500 - \$ 5,000	\$ 5,000 - \$10,000
R156-17b-502(1)	\$ 250 - \$ 500	\$ 2,000 - \$10,000
R156-17b-502(2) (a)	\$ 250 - \$ 500	\$ 500 - \$ 750
R156-17b-502(2) (b)	\$ 500 - \$ 2,000	\$ 2,500 - \$10,000
R156-17b-502(3)	\$ 100 - \$ 500	\$ 500 - \$ 1,000
R156-17b-502(4)	\$ 50 - \$ 100	\$ 200 - \$ 300
R156-17b-502(5)	\$ 100 - \$ 200	\$ 200 - \$ 500
R156-17b-502(6)	\$ 500 - \$ 1,000	\$ 2,000 - \$10,000
R156-17b-502(7)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
R156-17b-502(8)	\$ 100 - \$ 250	\$ 300 - \$ 500
R156-17b-502(9) (a)	\$ 50 - \$ 100	\$ 250 - \$ 500
R156-17b-502(9) (b)	\$ 250 - \$ 500	\$ 750 - \$ 1,000
R156-17b-502(10)	\$ 500 - \$ 2,000	\$ 2,000 - \$10,000
R156-17b-502(11)	\$ 100 - \$ 500	\$ 500 - \$ 1,000
R156-17b-502(12) (a)	\$ 100 - \$ 250	\$ 500 - \$ 2,500
R156-17b-502(12) (b)	\$ 250 - \$ 1,000	\$ 500 - \$ 5,000
R156-17b-502(13) (a)	\$ 50 - \$ 100	\$ 250 - \$ 500
R156-17b-502(13) (b)	\$ 250 - \$ 500	\$ 1,000 - \$ 2,000
R156-17b-502(14) (a)	\$ 500 - \$2,500	\$ 5,000 - \$10,000
R156-17b-502(14) (b)	\$ 2,000 per occurrence	
R156-17b-502(15)	double original penalty, up to	\$10,000
R156-17b-502(16)	\$ 500 - \$2,000	\$ 2,000 - \$10,000
R156-17b-502(17)	\$ 1,000 - \$5,000	\$10,000
R156-17b-502(18)	\$ 500 - \$2,500	\$ 5,000 - \$10,000
R156-17b-502(19)	\$ 100 - \$500	\$ 200 - \$ 1,000
R156-17b-502(20)	\$ 100 - \$500	\$ 200 - \$ 1,000
R156-17b-502(21)	\$ 100 - \$500	\$ 200 - \$ 1,000
R156-17b-502(22)	\$ 500 - \$2,000	\$ 2,000 - \$10,000
R156-17b-502(23) (a)	\$ 100 - \$300	\$ 500 - \$ 1,000
R156-17b-502(23) (b)	\$ 250 - \$500	\$ 500 - \$ 1,250
R156-17b-502(24)	\$ 100 - \$500	\$ 500 - \$ 1,000
R156-17b-502(25)	\$ 500 - \$2,000	\$ 2,500 - \$10,000
R156-17b-502(26)	\$ 500 - \$2,000	\$ 2,500 - \$10,000
58-37-8	\$ 1,000 - \$5,000	\$ 5,000 - \$10,000
R156-37-502(1) (a)	\$ 500 - \$2,000	\$ 2,500 - \$10,000
R156-37-502(1) (b)	\$ 500 - \$2,000	\$ 2,500 - \$10,000
R156-37-502(2)	\$ 500 - \$2,000	\$ 2,500 - \$10,000
R156-37-502(3)	\$ 500 - \$2,000	\$ 2,500 - \$10,000

R156-37-502(4)	\$ 500 - \$2,000	\$ 2,500 - \$10,000
R156-37-502(5)	\$ 500 - \$2,000	\$ 2,500 - \$10,000
R156-37-502(6)	\$ 500 - \$2,000	\$ 2,500 - \$10,000
R156-37-502(7)	\$ 500 - \$2,000	\$ 2,500 - \$10,000
R156-37-502(8)	\$ 500 - \$2,000	\$ 2,500 - \$10,000
Any other conduct that constitutes Unprofessional or Unlawful conduct	\$ 100 - \$ 500	\$ 200 - \$ 1,000

R156-17b-602. Operating Standards - Pharmacy Intern.

A pharmacy intern may provide services including the practice of pharmacy under the supervision of a ~~[n approved]~~ pharmacist preceptor, ~~[as defined in Subsection 58-17b-102(50), provided]~~ if the pharmacy intern met the criteria [as established] in Subsection R156-17b-303a.

R156-17b-606. Operating Standards - ~~[Approved]~~ Pharmacist Preceptor.

(1) In accordance with Subsections 58-17b-601(1) and 58-17b-102(50), the operating standards for a pharmacist ~~[acting as a]~~ preceptor ~~[include]~~ are established in this section.

~~[(1)]~~ 2) [meeting the following criteria] A pharmacist preceptor shall:

(a) hold an active and good standing [a Utah] pharmacist license permitting practice in the jurisdiction where the pharmacist is acting as a preceptor [that is active and in good standing];

(b) [document engaging] have engaged in active practice as a licensed pharmacist for [not less than] at least one year immediately preceding the internship, in any jurisdiction; and

(c) [not be under any sanction which, when considered by the Division and Board, would be of such a nature that the best interests of the intern and the public would not be served] ensure the totality of the internship circumstances are safe and appropriate according to generally recognized industry standards of practice;

~~[(d)]~~ 3) A pharmacist preceptor may provide indirect, on-site supervision to:

~~[(1)]~~ a) [no more than] up to two pharmacy interns during a working shift, except as provided in Subsection ([11]) 3) (b);

~~[(11)]~~ b) up to five pharmacy interns at public-health outreach programs such as informational health fairs, chronic disease state screening and education programs, [and] or immunization clinics. [7 provided]

~~———— (A) the totality of the circumstances are safe and appropriate according to generally recognized industry standards of practice; and~~

~~———— (B) the preceptor has obtained written approval from the pharmacy interns' schools of pharmacy for the intern's participation; and~~

~~———— (c) refer to the intern training guidelines as outlined in the Pharmacy Coordinating Council of Utah Internship Competencies, October 12, 2004, as information about a range of best practices for training~~

interns;]

~~[(2)4] [maintaining adequate records to]~~ A pharmacist preceptor shall document the number of internship hours completed by the pharmacy intern, and ~~[evaluating]~~ evaluate the quality of the pharmacy intern's performance during the internship~~[+]~~.

~~[— (3) — completing the preceptor section of a Utah Pharmacy Intern Experience Affidavit found in the application packet at the conclusion of the preceptor/intern relationship regardless of the time or circumstances under which that relationship is concluded; and]~~

~~[(4)5] [being]~~ A preceptor is responsible for the pharmacy intern's actions related to the practice of pharmacy while the pharmacy intern is practicing ~~[as a pharmacy intern]~~ under the preceptor's supervision.

R156-17b-612a. Operating Standards - Prescription Devices.

(1) In accordance with Subsections 58-17b-601(1) and 58-17b-610.8, the operating standards for prescription devices are established in this section.

(2) The prescribing practitioner identified on the prescription document under Subsection 58-17-610.8(1) is the prescriber for the prescription device described in Subsection 58-17b-610.8(3).

(3) The pharmacist or pharmacy intern dispensing the prescription device shall determine the following:

- (a) an appropriate dispense quantity;
- (b) directions for device use; and
- (c) refill.

(4) Each prescription device dispensed by a pharmacist or pharmacy intern shall be:

- (a) dispensed in accordance with Subsection 58-17b-602(1)(a) through (e) and Section 58-17b-609; and
- (b) dispensed from a Class A or Class B pharmacy.

(5)(a) Notice of the prescription device dispense shall be conveyed to the prescribing practitioner in writing, by electronic transmission, or by telephone within five business days following the prescription device dispense.

(b) The prescription device dispense notice shall include the following:

- (i) pharmacy name;
- (ii) pharmacy phone number;
- (iii) patient;
- (iv) dispensed quantity;
- (v) directions for use; and
- (vi) refill.

R156-17b-612b. Operating Standards - Exhausted Prescription for Insulin.

(1) In accordance with Subsections 58-17b-601(1) and 58-17b-608.2(7), the operating standards for dispensing an exhausted prescription for insulin are established in this section.

(2) Under Subsection 58-17b-608.2(3), a refill for an exhausted prescription in an amount up to a supply for 60 days may be for the

nearest available package size.

(3) The pharmacist who dispenses a refill of an exhausted prescription of insulin shall obtain:

(a) the prescribing information for the insulin;

(b) prescription directions; and

(c) other documentation based on the pharmacist's clinical judgment.

(4) The pharmacist shall document the following on the exhausted prescription refill hard copy or in the medication profile system:

(a) the information described in Subsection (3);

(b) the method of the attempt under Subsection 58-1b7-608.2(5)(a) to contact the patient's prescribing practitioner; and

(c) the method of the notification to the patient under Subsection 58-17b-608.2(5)(b) regarding the outcome of the attempt to contact the prescribing practitioner.

(5) An exhausted prescription refill label shall state "exhausted prescription".

R156-17b-614d. Operating Standards - Class B - Nuclear Pharmacy.

(1) In accordance with Subsection 58-17b-601(1), the operating standards for a Class B pharmacy designated as a nuclear pharmacy [~~shall have the following:~~] are established in this section.

(~~[1]~~2) A nuclear pharmacy shall have the following:

(a) have applied for or possess a current Utah Radioactive Materials License; and

(b) adequate space and equipment commensurate with the scope of services required and provided.

(~~[2]~~3) Nuclear pharmacies shall only dispense radiopharmaceuticals that comply with acceptable standards of quality assurance.

(~~[3]~~4) Nuclear pharmacies shall maintain a library commensurate with the level of radiopharmaceutical service to be provided.

(~~[4]~~5)(a) A licensed Utah pharmacist shall be immediately available on the premises at [~~all~~]any time[s] when the facility is open or available to engage in the practice of pharmacy.

(~~[5]~~b) In addition to Utah licensure, the pharmacist shall have classroom and laboratory training and experience as required by the Utah Radiation Control Rules.

(6) This rule does not prohibit:

(a) a licensed pharmacy intern or technician from acting under the direct supervision of a [~~n-approved~~] pharmacist preceptor who meets the requirements to supervise a nuclear pharmacy; or

(b) a Utah Radioactive Materials license from possessing and using radiopharmaceuticals for medical use.

(7) A hospital nuclear medicine department or an office of a physician[~~/~~]-surgeon, osteopathic physician[~~/~~]-surgeon, veterinarian, [~~pediatric~~]podiatric physician or dentist that has a current Utah Radioactive Materials License does not require licensure as a Class B pharmacy.

(8) A nuclear pharmacy preparing sterile compounds [~~must~~]shall follow the USP-NF Chapter 797 Compound for sterile preparations.

(9) A nuclear pharmacy preparing medications for a specific person shall be licensed as a Class B - nuclear pharmacy if located in Utah, and as a Class D pharmacy if located outside of Utah.

R156-17b-614g. Operating Standards - Class A or Class B Pharmacy - Remote Dispensing Pharmacy.

(1) In accordance with Subsections 58-17b-102(58), 58-17b-601(1), 58-17b-612(1)(b), and 58-1-301(3), the ~~[following]~~ operating standards ~~[shall apply to]~~ for a remote dispensing pharmacy are established in this section. ~~[+]~~

~~(1)~~ (2) A remote dispensing pharmacy shall:

- (a) be a Class A or Class B pharmacy;
- (b) have a Class A or Class B pharmacy serve as its supervising pharmacy to oversee its operations; and
- (c) be located in an area of need as defined in Subsection R156-17b-102(4).

(2) (3) A remote dispensing pharmacy may not perform compounding.

~~(3)~~ (4) (a) The supervising pharmacy's PIC shall serve as the remote dispensing pharmacy's RDPIC, who is responsible for ~~[all]~~ any remote dispensing pharmacy operations.

(b) An RDPIC may not serve as the RDPIC for more than one remote dispensing pharmacy, unless approved by the Division in collaboration with the Board.

~~(4)~~ (5) ~~[Staffing and Supervision]~~ (a) At ~~[all]~~ any time[s] that a remote dispensing pharmacy is open and available to serve patients, its pharmacy technicians shall be physically or electronically supervised by a pharmacist from the supervising pharmacy, under Subsection 58-17b-102(70).

(b) In accordance with Subsections 58-17b-612(1)(b) and (d) a pharmacist may oversee the operation of up to two remote dispensing pharmacies simultaneously.

(c) Unless a pharmacist is physically present, a remote dispensing pharmacy shall be staffed by no more than two licensed pharmacy technicians.

(d) Each pharmacy technician staffing a remote dispensing pharmacy shall have at least 500 hours of pharmacy technician experience.

(e) (i) Adequate supervision by a pharmacist of a remote dispensing pharmacy shall include maintaining uninterrupted visual supervision and auditory communication with the site, and full supervisory control of the automated system, if applicable.

(ii) ~~[This]~~ A supervising pharmacist may not delegate supervision ~~[may not be delegated]~~ to any other person.

(5) (6) The supervising pharmacy shall maintain a surveillance system and telepharmacy system that provides for effective video and audio communication between supervising pharmacy personnel and remote dispensing pharmacy personnel and patients, that includes the following features:

- (a) provides an adequate number of views of the entire site;
- (b) facilitates adequate pharmacist supervision;
- (c) allows the appropriate exchanges of visual, verbal, and written

communication for patient counseling and other matters involved in the lawful transaction or dispensing of drugs;

(d) confirms that the drug selected to fill the prescription is the same as indicated on the prescription label and prescription; and

(e) is secure and HIPAA compliant as defined in R156-17b-102(64).

([6]7)(a) Each component of the telepharmacy system shall be in good working order.

(b) If a~~ny~~ component of the system is malfunctioning, the remote dispensing pharmacy shall immediately close to the public and remain closed until system corrections or repairs are completed, unless a pharmacist is present onsite.

([7]8)(a) The supervising pharmacy shall develop and include in both the supervising pharmacy's and the remote dispensing pharmacy's policies and procedures a plan for continuation of pharmaceutical services by the remote dispensing pharmacy in case of an emergency interruption~~[+]~~.

([a]b)(i) The plan shall address the timely arrival at the remote dispensing pharmacy of necessary personnel, and the delivery to the remote dispensing pharmacy of necessary supplies, within a reasonable period of time following the identification of an emergency need.

(ii) A pharmacist shall be available onsite at the remote dispensing pharmacy as soon as possible after an emergency, and shall notify the Division in writing if the time exceeds 24 hours.

([b]c) The plan may provide for alternate methods of continuation of the services of the remote dispensing pharmacy, including personal delivery of patient prescription medications from an alternate pharmacy location or on-site pharmacist staffing at the remote dispensing pharmacy.

([8]9) ~~Facility.~~

~~—~~ (a)(i) The remote dispensing pharmacy's security system shall ~~[allow for]~~ track~~[ing of]~~ entries into the remote dispensing pharmacy.

(ii) ~~The~~ ~~[and the]~~ RDPIC shall periodically review the record of entries.

(b) A remote dispensing pharmacy shall display a sign easily visible to the public that informs patients of the following:

(i) that the pharmacy is a remote dispensing pharmacy;

(ii) the location of the supervising pharmacy; and

(iii) that at the patient's request a pharmacist will counsel the patient using audio and video communication systems.

([9]10) ~~Records and Inspections.~~

~~—~~ (a)(i) The supervising pharmacy shall maintain records of ~~[all]~~ the orders entered into its information system, including orders entered from the remote dispensing pharmacy.

(ii) Electronic records shall be available to and accessible from both the remote dispensing pharmacy and the supervising pharmacy.

(iii) The original records of the controlled substance prescriptions dispensed from the remote dispensing pharmacy shall be maintained at the remote dispensing pharmacy.

(b) The remote dispensing pharmacy shall retain a recording of surveillance, excluding patient communications, for at least 45 days.

(c) (i) The RDPIC shall oversee documented monthly inspections of the

remote dispensing pharmacy.

(ii) Documentation of ~~[such]~~the inspections shall be kept for five years, and shall include:

(~~[(1)]~~A) maintenance and reconciliation of ~~[all]~~any controlled substance~~[s]~~;

(~~[(1)]~~B) a perpetual inventory of Schedule II controlled substances;

(~~[(1)]~~C) temperature logs of the refrigerator and freezer that hold medications; and

(~~[(1)]~~D) the RDPIC's periodic review of the record of entries into the remote dispensing pharmacy.

R156-17b-626. Operating Standards - Appropriate Substitutes for Albuterol.

(1) In accordance with Subsections 58-17b-601(1) and 58-17b-605(9), a pharmacist or pharmacy intern may make appropriate substitutes for an albuterol inhaler with any brand or proprietary name albuterol product that has the same milligram dose per actuation.

(2) The pharmacist or pharmacy intern shall document an albuterol substitution on the prescription hard copy or in the medication profile system.

R156-17b-[904]901. [~~Criteria for Eligible Prescription Drug -- Beyond use Date or Expiration Date.~~] Operating Standards - Charitable Prescription Drug Recycling Program.

(1) In accordance with Sections 58-17b-903 and 58-17b-907, the operating standards for implementation of the Charitable Prescription Drug Recycling Program under Title 58, Chapter 17b, Part 9, Charitable Prescription Drug Recycling Act, are established in this section.

(2) The Division~~[~~
~~—The division]~~ in collaboration with the board has not established a date later than the beyond use date or the expiration date recommended by the manufacturer for a specific prescription drug.[

~~R156-17b-905. Fees.~~

(3) As authorized by Subsection 58-17b-905(2)(e), an eligible pharmacy may charge the following handling fees:

(~~[(1)]~~a) ~~[B]~~before accepting a prescription drug under the program: \$0 - \$10; and

(~~[(2)]~~b) ~~[B]~~before dispensing a prescription drug under the program: \$0 - \$5.[

~~R156-17b-907a. Registration Requirements -- Eligible Pharmacy.~~

(~~[(1)]~~4) A pharmacy seeking registration with the ~~[d]~~Division as an eligible pharmacy shall submit an application on a form provided by the ~~[d]~~Division and establish that:~~[-~~

~~—(2) The division's form shall at a minimum require the applicant pharmacy to establish that:]~~

(a) the applicant is currently licensed and in good standing with the ~~[d]~~Division;

(b) the applicant agrees to maintain, subject to inspection by the [d]Division, written standards and procedures in compliance with [Section R156-17b-907e] Subsection (6);

(c) the applicant agrees to create and maintain, subject to inspection by the [d]Division, a special training program in accordance with [Section R156-17b-907e] Subsection (8); and

(d) ~~[as required by] the applicant meets the requirements of Subsection 58-17b-902(8) (b) [the applicant is operated by a county, county health department, a pharmacy under contract with a county health department, the Department of Health, the Division of Substance Abuse and Mental Health, or a charitable clinic].~~

~~R156-17b-907b. Formulary.]~~

(5) The formulary established under Subsection 58-17b-907(2) shall include ~~[all]~~each prescription drug[s] approved by the federal Food and Drug Administration that meet Section 58-17b-904 criteria, except for:

(~~[1]~~)a) controlled substances;

(~~[2]~~)b) compounded drugs; and

(~~[3]~~)c) drugs that can only be dispensed to a patient registered with the drug's manufacturer per federal Food and Drug Administration requirements.

~~R156-17b-907c. Standards and Procedures -- Eligible Pharmacies.]~~

(6) An eligible pharmacy shall maintain written standards and procedures available for inspection by the division that:

(~~[1]~~)a) satisfy the requirements of Section 58-17b-907; and

(~~[2]~~)b) satisfy labeling requirements of Subsections 58-17b-602(5) through (8), and ensure that labels clearly identify the eligible drug was dispensed under the program.

~~R156-17b-907d. Standards and Procedures -- Facilities and Mental Health and Substance Abuse Clients.]~~

(~~[1]~~)7(a) In accordance with Subsection 58-17b-907(4)(a), the division shall schedule and facilitate an annual meeting between the Department of Health and eligible pharmacies to establish program standards and procedures for assisted living facilities and nursing care facilities~~[, and]~~.

(~~[2]~~)b) In accordance with Subsection 58-17b-907(4)(b), the division shall schedule and facilitate an annual meeting between the Division of Substance Abuse and Mental Health and eligible pharmacies to establish program standards and procedures for mental health and substance abuse clients.

~~R156-17b-907e. Special Training Program.]~~

(8) An eligible pharmacy shall:

(~~[1]~~)a) create and maintain a special training program that its pharmacists and licensed pharmacy technicians shall complete before participating in the program; and

(~~[2]~~)b) maintain a record for at least two years of ~~[all]~~each

pharmacist[s] and licensed pharmacy technician[s] that [~~have~~has] completed the special training program.

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